§483.75 Quality Assurance and Performance Improvement

Phase 3 Requirements

Division of Nursing Homes

Welcome to the Quality Assurance and Performance Improvement (QAPI) Phase 3 training.

Overview of Phase 3 Requirements

- New requirements in F865 for the Quality Assurance and Performance Improvement (QAPI) plan and program,
- Requirements in F866 have been relocated
- New requirements for the QAPI program, feedback, data collection, analysis and monitoring, and improvement activities
- Expansion of required Quality Assessment and Assurance (QAA) required committee members
- New QAPI training requirements

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This training will provide an overview of the Quality Assurance and Performance Improvement, also known as QAPI, requirements which went into effect in November 2019.

Today we will cover

- New requirements in F865 for the QAPI plan and program,
- The relocation of the requirements in F866,
- New requirements for the QAPI program, including feedback, data collection, analysis, monitoring, and improvement activities,
- The expansion of Quality Assessment and Assurance (QAA) Committee required members, and
- The new QAPI training requirements.

F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- §483.75(a) Quality assurance and performance improvement (QAPI) program. Each LTC facility, including a facility that is part of a multiunit chain, must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. The facility must:
- §483.75(a)(1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;
- §483.75(a)(3) Present its QAPI plan to a State Survey Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and
- §483.75(a)(4) Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a State Survey Agency, Federal surveyor or CMS upon request.

A quality assurance and performance improvement (QAPI) program takes a systematic, interdisciplinary, comprehensive, and data-driven approach to maintaining and improving safety and quality. An interdisciplinary approach encompasses all managerial, and clinical, services, which includes care and services provided by outside (contracted or arranged) providers and suppliers.

Phase 3 Requirements for 483.75(a) in F865 lay out the requirements of the facility's QAPI program.

Each facility must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life.

Each facility must also maintain documentation and provide evidence of its ongoing QAPI program.

Demonstration of compliance includes, but is not limited to:

- Evidence of systems and reports demonstrating identification, reporting, investigation, analysis and prevention of adverse events;
- Data collection and analysis at regular intervals; and
- Documentation demonstrating development, implementation and evaluation of

corrective actions or performance improvement activities.

Additionally, each facility must present its QAPI plan to State and Federal surveyors at each annual recertification survey and upon request during any other survey, and to CMS upon request.

F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- §483.75(b) Program design and scope.
  A facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility. It must:
- §483.75(b)(1) Address all systems of care and management practices;
- §483.75(b)(2) Include clinical care, quality of life, and resident choice;
- §483.75(b)(3) Utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents of a SNF or NF.
- §483.75(b) (4) Reflect the complexities, unique care, and services that the facility provides.

Phase 3 requirements also specify that Each facility must design a QAPI program that is ongoing, comprehensive and capable of addressing the full range of care and services it provides.

At a minimum, the program must:

- Address all systems of care and management practices;
- Include clinical care, quality of life and resident choice;
- Utilize the best available evidence to define measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents; and
- Reflect the complexities, unique care and services that the facility provides.

Effective QAPI programs address systems of care and management practices. Systems of care (or care delivery systems) are the processes in place to achieve an expected clinical outcome. Facilities may have many systems of care which intersect and involve multiple disciplines and departments. For example, the system for prevention of pressure ulcers also involves the system for ensuring adequate nutrition, as well as the systems for identification of changes in condition and infection prevention.

In addition to systems of care, the facility should monitor important management practices

such as resident finances and personal funds, admission and discharge practices, and other services that impact quality of life and resident rights. The QAPI program should address quality of life and resident choice by identifying the unique needs and preferences of the varying demographics of residents residing in the facility (i.e., young and/or culturally diverse residents) and seeking ongoing input and feedback from their residents.

F865 QAPI Program, Plan, Disclosure, Good Faith Attempt

- §483.75(f) Governance and leadership.
  The governing body and/or executive leadership (or organized group or individual who assumes full legal authority and responsibility for operation of the facility) is responsible and accountable for ensuring that:
- §483.75(f)(1) An ongoing QAPI program is defined, implemented, and maintained and addresses identified priorities.
- §483.75(f)(2) The QAPI program is sustained during transitions in leadership and staffing;
- §483.75(f)(3) The QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed;
- §483.75(f)(4) The QAPI program identifies and prioritizes problems and opportunities that reflect organizational process, functions, and services provided to residents based on performance indicator data, and resident and staff input, and other information.
- §483.75(f)(5) Corrective actions address gaps in systems, and are evaluated for effectiveness;
- §483.75(f)(6) Clear expectations are set around safety, quality, rights, choice, and respect.

The governance and leadership requirements are also part of Phase 3
The governing body and/or executive leadership (or organized group or an individual who assumes full legal authority and responsibility for operation of the facility) must ensure the QAPI Program:

- Is defined, implemented and ongoing;
- Addresses identified priorities;
- Is sustained through transitions in leadership and staffing;
- Has adequate resources, including staff time, equipment, and technical training as needed;
- Uses performance indicator data, resident and staff input, and other information to identify and prioritize problems and opportunities;
- Implements corrective actions to address gaps in systems and evaluates actions for effectiveness; and
- Establishes clear expectations around safety, quality, rights, choice and respect

Investigation & Key Elements for F865

Surveyors will use the facility task QAPI and QAA Review when determining if the facility meets the requirements for, or investigating concerns related to requirements in F865.

The Key Elements of Non-Compliance have been updated to include the new requirements discussed.

Surveyors will use the facility task QAPI and QAA Review along with the guidance when determining if the facility meets the requirements for or when investigating concerns related to requirements in F865.

Additionally, the Key Elements of Non-Compliance for F865 have been updated to include the new requirements discussed.

Key Elements of Non-Compliance

The facility failed to do any one of the following:

- Maintain documentation and evidence of its ongoing QAPI program;
- Present its QAPI plan to the Federal and/or State surveyors during recertification survey or upon request;
- Present QAPI evidence necessary to demonstrate compliance with these requirements;
- Develop, implement and maintain an effective, comprehensive QAPI program, that addresses the full range of services the facility provides; and
- Ensure governing body oversight of the facility's QAPI program and activities.

New Key Elements of Non-compliance in F865 have been added. To cite a deficiency, determine if the facility failed to:

- Maintain and present any evidence related to QAPI program, or
- Present its' QAPI plan to surveyors during recertification survey or upon request or
- Develop, implement and maintain an effective QAPI program, or
- Ensure governing body oversight of the QAPI program and activities

F866 QAPI/QAA Data Collection & Monitoring

F866

Note: Regulatory requirements §483.75(c) and §483.75(c)(1)-(4) have been relocated to F867.

You may be wondering what happened to F866 the QAPI/QAA Data Collection and Monitoring tag. In the course of writing the Phase 3 guidance, we found that the components of F866 and F867 were similar and intertwined, so we combined the requirements into one tag. Therefore, the requirements from F866 were relocated into F867.

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(c) Program feedback, data systems and monitoring. A facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring, including adverse event monitoring. The policies and procedures must include, at a minimum, the following:
- §483.75(c)(1) Facility maintenance of effective systems to obtain and use of feedback and input from direct care staff, other staff, residents, and resident representatives, including how such information will be used to identify problems that are high risk, high volume, or problem-prone, and opportunities for improvement.
- §483.75(c)(2) Facility maintenance of effective systems to identify, collect, and use data and information from all departments, including but not limited to the facility assessment required at §483.70(e) and including how such information will be used to develop and monitor performance indicators.

With the exception of the requirements for the QAA Committee to develop and implement plans of action to correct identified quality deficiencies, most of the requirements in F867 are Phase 3 requirements that became effective in November 2019.

As required in §483.75(a) (F865), the facility must develop and implement written policies and procedures that ensure the care and services it delivers meet acceptable standards of quality in accordance with recognized standards of practice. This is accomplished, in part, by identifying, collecting, analyzing and monitoring data which reflects the functions of each department and outcomes to residents.

Feedback is one of many data sources which provide valuable information the facility must incorporate into an effective QAPI program. Each facility must establish and implement written policies and procedures for feedback.

Feedback must be obtained from direct care staff, other staff, residents and resident representatives, as well as other sources, and be used to identify problems that are high-risk, high-volume, and/or problem-prone, as well as opportunities for improvement. Feedback from residents is necessary to understand what quality concerns are important to them, their perspectives, values and priorities, as well as the impact of the facility's daily routines on their physical, mental, and psychosocial well-being. Staff can also provide

valuable input into understanding care and service delivery processes.

A facility should choose the best mechanism for feedback to support their QAPI program. Examples of ways a facility can obtain resident and staff feedback may include, but are not limited to: satisfaction surveys and questionnaires; routine meetings, such as care plan, resident council, safety team, or town hall meetings; and suggestion or comment boxes

Effective feedback systems in a QAPI program also include methods for providing feedback to direct care staff, other staff, residents and representatives. This may involve including these individuals in problem solving, various meetings or providing updates and communicating facility system changes.

In order to ensure care and services are carried out consistently, accurately, timely and according to recognized standards of quality, the facility must collect and monitor data reflecting its performance, including adverse events.

Facility policies and procedures must address how data will be identified, and the frequency and methodology for collecting and using data from all departments. The facility determines what data it will collect to represent its care areas considered to be associated with high-risk, high-volume, and/or problem-prone issues.

Data collection can be done using several methods, such as audit tools (purchased or developed by the facility), direct observation, interview, or testing. Sources for data may include the Minimum Data Set (MDS) and Quality Measures, medical records, survey results, incident reports, complaints, suggestions and staffing data. CMS expects the data collection methodology to be consistent, reproducible and accurate to produce data that are valid and reliable, and support all departments and the facility assessment required in §483.70(e).

It is not necessary to collect all data at the same frequency, and the facility may develop a schedule for routine data collection. For example, data related to high-risk or problem-prone issues will generally be collected more frequently such as daily, weekly, or monthly, until performance is at a satisfactory level, then collected less frequently (e.g. quarterly or every six months).

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(c)(3) Facility development, monitoring, and evaluation of performance indicators, including the methodology and frequency for such development, monitoring, and evaluation.
- §483.75(c)(4) Facility adverse event monitoring, including the methods by which the facility will systematically identify, report, track, investigate, analyze and use data and information relating to adverse events in the facility, including how the facility will use the data to develop activities to prevent adverse events.

The facility must have policies and procedures in place for developing, monitoring and evaluating performance indicators, as well as describe how and with what frequency the facility develops, monitors and evaluates its performance indicators.

A performance indicator is a measurement of from the data collected, which represents performance in a specific care or service area. Performance indicators enable the facility QAA Committee to establish performance thresholds and goals, identify deviations in performance and evaluate progress. An example of monitoring includes comparing results of facility performance over time, as well as to state or national benchmarks.

Nursing homes must develop and implement written policies and procedures that enable the facility to systematically identify and investigate medical errors and adverse events, including how the facility will analyze and use data relating to errors and events to develop activities to prevent future occurrences.

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(d) Program systematic analysis and systemic action.
- §483.75(d)(1) The facility must take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained.
- §483.75(d)(2) The facility will develop and implement policies addressing:

  (i) How they will use a systematic approach to determine underlying causes of problems impacting larger systems;

  (ii) How they will develop corrective actions that will be designed to effect change at the systems level to prevent quality of care, quality of life, or safety problems; and

  (iii) How the facility will monitor the effectiveness of its performance improvement activities to ensure that improvements are sustained.

As part of its' QAPI program, each facility is responsible for having systems in place and implementing actions which will improve performance. To ensure improvements are achieved and sustained, facilities should implement corrective actions, measure the success of these actions, and track their performance.

Additionally, the facility must develop and implement policies and procedures which address how it will use systematic approaches to assist in determining underlying causes of problems which impact larger systems. These approaches may include root cause analysis, reverse tracker methodology, or health-care failure and effects analysis.

Policies and procedures must also address how the facility will develop corrective actions that will make changes at the systems level to prevent quality of care, quality of life, or safety problems, as well as how the facility will monitor the effectiveness of its performance improvement activities to ensure improvements are sustained.

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(e) Program activities.
  §483.75(e)(1) The facility must set priorities for its performance improvement activities that focus on high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, resident safety, resident autonomy, resident choice, and quality of care.
- §483.75(e)(2) Performance improvement activities must track medical errors and adverse resident events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the facility.
- §483.75(e)(3) As part of their performance improvement activities, the facility must conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility must reflect the scope and complexity of the facility's services and available resources, as reflected in the facility assessment required at §483.70(e). Improvement projects must include at least annually a project that focuses on high risk or problem-prone areas identified through the data collection and analysis described in paragraphs (c) and (d) of this section.

As part of its QAPI program activities, the facility must establish priorities for performance improvement activities that focus on resident safety, health outcomes, autonomy, choice and quality of care, as well as high-risk, high-volume, and/or problem-prone areas. When determining priorities, the facility must also consider the incidence, prevalence and severity of problems or potential problems which it has identified.

If systemic concerns, such as repeat survey deficiencies, have not been identified or prioritized by the facility's QAA committee, this may indicate that the committee is not effectively performing its required functions.

In addition to the improvement activities the facility has identified as priorities, the facility must also track medical errors and adverse resident events. When the facility identifies medical errors or adverse resident events, the facility must analyze the cause of the error or event, implement corrective actions to prevent future events, and conduct monitoring to ensure it has achieved the desired outcome and keeps the outcome going.

As part of the facility's performance improvement activities to reduce medical errors and adverse events, feedback and learning must be provided throughout the facility. Educating staff, residents, resident representatives and family members on medical errors and adverse events, such as what to look for and preventive measures, are important factors in

reducing and preventing medical errors and adverse resident events.

The facility must conduct distinct performance improvement projects, based on the scope and complexity of facility services and available resources, identified as a result of the facility assessment required at §483.70(e). While the number and frequency of improvement projects may vary, each facility must conduct at least one improvement project annually that focuses on high-risk or problem-prone areas, identified by the facility through data collection and analysis.

The facility's action plans to address quality deficiencies and improve performance may be implemented in a variety of ways, including: staff training and deployment of changes to procedures; monitoring and feedback mechanisms; and processes to revise plans that are not achieving or sustaining desired outcomes. The committee may delegate the implementation of action plans to various facility staff and/or outside consultants.

F867 Data Collection, Monitoring, Analysis & Improvement

- §483.75(g) Quality assessment and assurance.
- §483.75(g)(2) The quality assessment and assurance committee reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section. The committee must:

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  (iii) Regularly review and analyze data, including data collected under the QAPI program and data resulting from drug regimen reviews, and act on available data to make improvements.

Functioning under the facility's governing body, the QAA committee is responsible for:

- Developing and implementing appropriate plans of action to correct identified deficiencies;
- Regularly reviewing and analyzing data, including data collected under the QAPI program and data resulting from drug regimen reviews; and
- Acting on available data to make improvements.

Investigation & Key Elements for F867

Surveyors will use the facility task QAPI and QAA Review along with the interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to requirements in F867.

The Key Elements of Non-Compliance have been updated to include the new requirements discussed.

Surveyors will use the facility task QAPI and QAA Review along with the interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to requirements in F867.

Additionally, the Key Elements of Non-Compliance for F867 have been updated to include the new requirements discussed.

F868 QAA Committee

- §483.75(g) Quality assessment and assurance.
  §483.75(g)(1) A facility must maintain a quality assessment and assurance committee consisting at a minimum of:

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  (iv) The infection preventionist.

- §483.80(c) [Infection preventionist] participation on quality assessment and assurance committee.

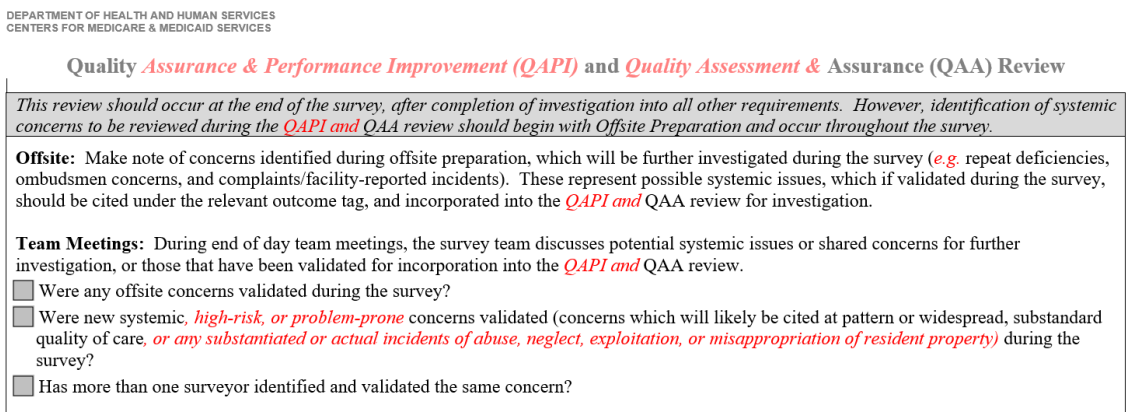
  The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.

F868 contains a new Phase 3 requirement that identifies the infection preventionist (IP) as a required member of the facility's QAA Committee.

The IP must report on the facility's infection prevention and control program, and on incidents such as healthcare-associated infections, identified under the program on a regular basis. Reporting may include, but is not limited to, facility process and outcome surveillance, outbreaks and control measures, communicable illnesses such as TB or influenza and the Antibiotic Stewardship Program. In order to be considered an active participant, the infection preventionist should attend each QAA meeting. If unable to attend, another staff member should report on the infection preventionist's behalf, but this does not change or absolve the IP's responsibility to fulfill the role of QAA committee member or reporting on the facility's infection prevention and control program.

For concerns related to the *infection preventionist's responsibilities and qualifications*, refer to F882 Infection preventionist qualifications and role.

QAPI & QAA Review (CMS 20058)



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Quality *Assurance & Performance Improvement (QAPI)* and *Quality Assessment &* Assurance (QAA) Review

This review should occur at the end of the survey, after completion of investigation into all other requirements. However, identification of systemic concerns to be reviewed during the QAPI and QAA review should begin with Offsite Preparation and occur throughout the survey.

Offsite: Make note of concerns identified during offsite preparation, which will be further investigated during the survey (*e.g.* repeat deficiencies, ombudsmen concerns, and complaints/facility-reported incidents). These represent possible systemic issues, which if validated during the survey, should be cited under the relevant outcome tag, and incorporated into the *QAPI and* QAA review for investigation.

Team Meetings: During end of day team meetings, the survey team discusses potential systemic issues or shared concerns for further investigation, or those that have been validated for incorporation into the *QAPI and* QAA review.

- ☐ Were any offsite concerns validated during the survey?
- ☐ Were new systemic*, high-risk, or problem-prone* concerns validated (concerns which will likely be cited at pattern or widespread, substandard quality of care*, or any substantiated or actual incidents of abuse, neglect, exploitation, or misappropriation of resident property)* during the survey?
- ☐ Has more than one surveyor identified and validated the same concern?

As you heard us mention during the training, the facility task QAPI and QAA Review has been updated to include the new requirements and is available in the survey resources folder.

Surveyors are to use the facility task at the end of the survey, after completion of investigation into all other requirements, to evaluate facility compliance and when investigating concerns related to QAPI and QAA.

Where to Investigate

- F865: For concerns related to whether a facility has implemented and maintains a comprehensive QAPI program and plan, disclosure of records and governance and leadership.
- F867: For concerns related to how the facility obtains feedback, collects data, monitors adverse events, identifies areas for improvement, prioritizes improvement activities, implements corrective and preventive actions, and conducts performance improvement projects.
- F868: For concerns related to the composition of the QAA committee, frequency of meetings and reporting to the governing body.

Okay, so lets talk about where the surveyor will investigate concerns related to the facility's QAPI program and QAA Committee.

For concerns related to implementation and maintenance of a comprehensive QAPI program and plan, disclosure of QAPI records, and governance and leadership, refer to F865.

For concerns related to feedback, data collection, monitoring adverse events, identifying areas for improvement, prioritization of improvement activities, implementation of corrective and preventive actions, and performance improvement project, refer to F867.

And lastly, for concerns related to the QAA committee members, frequency of meeting and reporting activities to the governing body, refer to F868.

F944 QAPI Training

§483.95(d) Quality assurance and performance improvement.

A facility must include as part of its QAPI program mandatory training that outlines and informs staff of the elements and goals of the facility's QAPI program as set forth at §483.75.

We want to remind you about the new QAPI Training requirements in F944. Please view the CMS Training presentation and Appendix PP of the SOM for additional information.

Summary

New QAPI and QAA requirements are located in Appendix PP of the State Operations Manual (SOM) located at:

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes

We have covered a lot of information today, thank you for staying with us. Please remember that this training serves as an overview of the requirements and interpretive guidance, and that the new requirements, additional guidance and examples are included in Appendix PP of the SOM, which is available on the CMS website listed on the slide.

Questions

Thank you for your continued efforts towards our shared goal in providing quality care to America's nursing home residents.

Submit all questions about §483.75 Quality Assurance and Performance Improvement to the DNH Triage mailbox:

DNH_TriageTeam@cms.hhs.gov

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Again, we thank you for taking the time to participate in this training and for your continued efforts towards our shared goal in providing quality care to America's nursing home residents

For questions about the requirements for QAPI in §483.75, please email the DNH Triage mailbox at: DNH_TriageTeam@cms.hhs.gov